REMARKS

The Examiner rejected claim 8 under 35 U.S.C. 112, first paragraph, contending that the specification does not enable the claimed *prevention* of the recited conditions. Applicants note that the Examiner does, however, acknowledge that the specification supports the *treatment* of the same conditions. Respectfully, the same parts of the specification that the Examiner has acknowledged as supporting treatment of the conditions also support the prevention of the conditions. For example, the specification provides detailed guidance for dosage regimens. In view of that information, it would not take undue experimentation to follow such dosage regimens and then determine whether the recited conditions have been prevented. For at least this reason, Applicants request withdrawal of this rejection.

The Examiner also rejected claims 1-8 as being unpatentable under 35 U.S.C. 103 over Bollinger '122 in view of Richter '843 and in further view of Windholz and Osol. According to the Examiner, Bollinger teaches parenteral or intravenous compositions of Applicants' recited cyclosporin, but fails to teach or suggest the use of oleic acid and ethanol as components of the compositions. To remedy this difference between Bollinger '122 and the claims, the Examiner relies on the secondary references for teachings related to oleic acid and ethanol containing compositions. Based on this combination of the references, the Examiner concludes that Applicants' claims would have been obvious to one of ordinary skill in the art.

Applicants traverse this rejection. MPEP 2143.03 mandates that for a section 103 rejection to be sustainable, "all the claim limitations must be taught or suggested by the prior art." The rejection at hand fails to consider Applicants' claim recitation that "the concentration is free of poly(oxyethylene)-40-castor oil." On this basis alone, the rejection should be withdrawn.

Moreover, MPEP 2143.02 requires that "at least some degree of predictability is required" in the prior art when the Patent Office relies on prior art under section 103. Here, the references do not teach or suggest that Applicants' *specific* active agent can be successfully formulated with ethanol and oleic acid *in the absence of poly(oxyethylene)-40-castor oil*. The rejection fails to give any reasonable scientific rationale as to why there would have been at least some measure of predictability in the prior art that Applicants' claimed formulation would work. The lack of any consideration of any aspect of this claim recitation is indicative of the impermissible hindsight reconstruction upon which the rejection is based.

For at least these reasons, Applicants respectfully request that the rejection be withdrawn.

Applicants also request withdrawal of the Examiner's objection to claim 6 as claim 6 has been cancelled.

If there are any additional fees due in connection with this communication, including any fees for an extension of time, Applicants request such an extension of time and the Commissioner is authorized to charge such fees to Deposit Account No. 19-0134 in the name of Novartis Corporation.

Respectfully submitted,

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